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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/980,395 11/28/97 SONTHEIMER H D5858D1

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HM12/0718

EXAMINER

SUN HOFFMAN, L

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 07/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/980,395

Applicant(s)

Sonthelmer et al

Examiner

Lin Sun-Hoffman

Group Art Unit
1642



☒ Responsive to communication(s) filed on May 11, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1 and 4 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 4 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Response to the Office Action filed on 5-11-00 has been received.

Claims 1 and 4 are examined on the merits.

Rejection maintained:

Double Patenting

2. Claims 1 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 21 of copending Application No. 08980394. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to a pharmaceutical composition, which comprising a ligand that binds specifically glial-derived or meningioma-derived tumor cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by DeBin et al (Am. J. Physiol. 264/2, 33-2 (C361-C369), 1993).

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Claim 1 is drawn to a pharmaceutical composition, which binds specifically to glial-derived or meningioma-derived tumor cells comprising a chlorotoxin ligand and a pharmaceutically acceptable carrier.

DeBin et al teach a chlorotoxin which specifically blocks chloride channels (see abstract), The property of the specificity to the glioma chloride channel is an inherent property of the chlorotoxin taught by DeBin et al. as evidenced by the instant specification. DeBin et al teach purified chlorotoxin in water which is considered to be a pharmaceutically acceptable carrier (page 363, column 2, 3rd full paragraph). The preamble recitation of "pharmaceutical composition" is a statement of intended use and is not given weight for the purpose of comparing the claim with the prior art. The claim reads on the components per se which are chlorotoxin and a pharmaceutical carrier. The composition taught by the DeBin et al. is identical to that claimed. Therefore, DeBin et al. anticipate claim 1.

Applicants argue that DeBin does not teach that chlorotoxin can be used in the treatment of gliomas and meningiomas. However, the argument is found unpersuasive. Chlorotoxin is a compound known in the prior art, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (See MPEP 2112). Since the reference teaches a composition, i.e., chlorotoxin, the specificity to glial-derived or meningioma-derived tumor cells is an inherent property of chlorotoxin.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeBin et al (Am. J. Physiol. 264/2, 33-2 (C361-C369), 1993) in view of Hammock et al (US Patent Number: 5756340, filed May 8, 1995) further in view of Hosli et al (Exp Brain Res, 80, 621-625, 1990).

DeBin et al teach as set forth above. However, DeBin et al differ from the instant invention in failing to disclose a labeled chlorotoxin. Hammock et al teach a labeling of toxins and their use in competitive binding assays in column 13, example 6. The list preferred toxins for practicing the invention includes chlorotoxin (see column 7 table 1, column 13, lines 45-59). Hammock et al. do not teach radiolabeled chlorotoxin in a carrier. Hosli et al teach that radiolabeled chloride channel ligands were known to be useful for receptor characterization (see page 621, column 2, Material and methods).

It would have been *prima facie* obvious for one of the ordinary skill in the art at the time the invention was made to make a radiolabeled chlorotoxin. One of ordinary skill in the art would have been motivated to radiolabel a chlorotoxin taught by DeBin et al. and Hammock et al. According to the methods taught by Hammock et al or Hosli et al., and to combine the radiolabeled chlorotoxin with a carrier for use in the methods taught by Hammock et al. or Hosli et al., one would have been motivated to do so in view of the explicit suggestion by Hammock et al. that radiolabeling of toxins used in accordance with their invention including chlorotoxin, was useful to characterize binding to insect neuronal tissues. One would further have been motivated by the teaching of Hosli et al. that radiolabeled chloride channel proteins' ligands of which

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chlorotoxin is one, are useful for receptor localization and detection. Moreover, one of the ordinary skills in the art would have been motivated to make a composition of radiolabeled chlorotoxin with a carrier such as water or buffer as taught by Hammock et al (column 13, lines 45-59), because it is well known to be useful for the storage and analytical purposes. In doing so, one would have arrived at the claimed invention.

Applicants argue that DeBin fails to teach that chlorotoxin could act as a targeting agent for a particular cell type, Hammock fails to teach the use for glial or meningioma tumor cells, and Hosli does not teach the pharmacological application of the ligands. However, the argument is found unpersuasive. The claims are drawn to a composition of radiolabeled chlorotoxin. The intended use does not carry any patentable weight. Moreover, the radiolabeling of a compound is a routine practice in the art for detection purposes, therefore, it would have been obvious to combine the teachings of these prior arts to make a radiolabelled chlorotoxin.

Conclusion

5. Claims 1 and 4 are not allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lin Sun-Hoffman, Ph.D., whose telephone number is (703)-308-7552. The examiner can normally be reached on Monday to Friday from 7:30 am to 4:00 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, Ph.D., can be reached on (703) -305-3995.

Lin Sun-Hoffman, Ph.D.

July 11, 2000



NANCY A. JOHNSON, PH.D.
PRIMARY EXAMINER